1651

Docket No.: 28341/6281A
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: McKim *et al.*

Application No.: 09/586,242 Group Art Unit: 1651

Filed: June 2, 2000 Examiner: Jean C. Witz

For: Improved Toxicity Screening Method

RESPONSE TO RESTRICTION REQUIREMENT DATED APRIL 22, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This paper is filed in response to an Office Action dated April 22, 2003, setting for a restriction requirement in the above-referenced application. A response is due on May 22, 2003. As such, this paper is timely filed and no fees are believed to be due. However, should any fees be deemed necessary in connection with the filing of this response, the Commissioner is hereby authorized to deduct any such fees from Marshall, Gerstein and Borun account number 13-2855.

The Office Action set forth a two-way restriction requirement between (I) methods of predicting the *in vivo* toxicity of a chemical compound (claims 1-27 and 37-38), and (II) methods of identification, prioritization and development of pharmaceutical compounds (claims 28 to 36). In addition, the Examiner also requested that Applicants elect a single disclosed species for each of the first second, third fourth and fifth indicators of cell health.

In response, to the restriction between Groups I and II, Applicants elect the claims of **Group I**, *i.e.*, claims 1-27 and 37-38. This election is made ***with traverse.*** The claims of Group I are all directed to methods of predicting the *in vivo* cytotoxicity of a chemical compound using a combination of at least three assays with different biochemical endpoints in order to predict the

in vivo toxicity of the compound (see claim 1). The claims of Group II use this method of predicting the *in vivo* cytotoxicity of the drug in order to develop an agent for treating a disease (claim 28, see step c), identify a lead compound for drug development (claim 31, see step b), screen and select a candidate substance (claim 34, see step b), prioritize candidate therapeutic agents for pharmaceutical research and development (claim 36, see step b). The claims of Group II are not independent from the claims of Group I. The claims of Group II are connected in design and operation to the claims of Group I because each of the claims of Group II necessary encompasses all of the elements of claim 1 of Group I.

Moreover, while Applicants agree that the invention of Group I has separate utility from the invention of Group II, the novelty and non-obviousness of the claims of Group II depends at least in part of the elements of the invention of Group I. As indicated in MPEP 806.05(c), if it cannot be shown that Group II "does not require the particulars of [Group I] as claimed for patentability (to show novelty and nonobviousness)," then the inventions are not distinct.

In light of the above comments Applicants believe that the claims of Group II are not independent and distinct from the claims of Group I. As such, Applicants request that the restriction requirement be withdrawn.

In response to the requirement for an election of species for each of the indicators of health, Applicants elect glutathione S-transferase assay as the first indicator of cell health, an ATP assay as the second indicator of cell health, cell number count as the third indicator of cell health, an MTT assay as the fourth indicator of cell health, and alamar blue assay as the fifth indicator. Applicants reserve the right to request reconsideration and rejoinder of the remaining species in accordance with 37 C.F.R. §1.141.

Applicants believe that each of the presently pending claims in this application is believed to be in condition for allowance. Should the Examiner have any further questions, she is invited to contact the undersigned.

Dated: May 22, 2003

Respectfully submitted,

By _____

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